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(72) Inventor: HARRY HENRY LeVEEN

1 533 204

(54) FLEXIBLE TUBING

(71) I, HARRY HENRY LeVEEN, a Citizen of the United States of America, of 800 Poly Place, Brooklyn, New York 11209, United States of America, do hereby declare the invention, for which I pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:-

This invention relates to flexible tubing which is particularly suitable for medical use, such as in catheters and the like.

In surgical and other hospital practice of medicine, the use of flexible tubing is necessary and commonplace. Tubes are used for catheters, for nasogastric suction, for administration of intravenous fluids and blood, to mention but a few uses. Occasionally tubing is implanted in the body permanently, as for the drainage of spinal fluid into the venous system or peritoneal cavity for hydrocephalus; or as for drainage of ascitic fluid in a periteneo-venous shunt. At other times tubing is temporarily inserted, as for taking venous pressure, or for infusing concentrated glucose solution into the *vena cava*.

Generally, there are two problems which are encountered in the medical use of tubing. The first of these is the problem caused by unnoticed, inadvertent kinking. The second problem arises from the need, particularly where the tubing is inserted or implanted within the body, to ascertain the location of the centre of the tubing, for example by radiography.

Generally tubing which is sufficiently flexible for medical use, as described above, must be constructed of material which is relatively flexible and must be constructed with relatively thin walls, not only to permit the necessary flexibility but also to accommodate flow through the tubing. Such tubing is subject, upon bending, to kinking and consequently collapse and blockage of flow. When the kinking inadvertently occurs and is unnoticed,

If the tubing is part of a urinary collecting system with drainage of the bladder by a catheter, the flow of urine is interrupted by kinking of the tubing and accumulates in the bladder. While this may not be catastrophic, in other circumstances the kinking of a drainage tube could cause fatal consequences. Consequently, non-kinkable tubing is achieved by utilizing thicker wall sections or by using stiffer materials, or by both. These corrective factors result in lowering the flexibility of the tubing to the point where it no longer is useful. Alternatively, steel or other resilient metal springs can be incorporated into the wall of plastic tubing by a complicated helical laminating process which not only is expensive but creates problems in terminating the tubing to avoid corrosion and the like. An additional problem encountered when metal wire is incorporated into the flexible tubing is that the tubing must often be transected in order to shorten it. This is accomplished with some difficulty since the spring wire is difficult to cut and cutting the tubing will expose the wire to the corrosive action of the tissues. In addition the exposed wire may pierce the lumen of the wall of the body structure in which the tube was placed. There are therefore good medical reasons why wire is less satisfactory as an anti-kinking means in flexible tubing, which as well as the problems encountered in the manufacture of wire containing tubing, make such tubing undesirable.

It has therefore been proposed in utilizing tubing, either introduced into or implanted within the body, that the tubing be made radiopaque. This results in tubing which is not optically translucent, and therefore presents problems in determining the presence and position of foreign matter and the like when the tubing is cleaned and sterilized. One solution to the latter problem is the co-extrusion of a radiopaque stripe in the wall of otherwise translucent tubing (U.S. Patent

indication of the size of the lumen, and hence of its centre, and also are a poor indication that a section of tubing has kinked.

It is accordingly a principal object to the present invention to provide a flexible tubing suitable for medical use which is highly resistant to kinking. It is a further object of this invention to provide such tubing in which the size of the tubing and the presence of a kink are immediately apparent on radiography, but in which the tubing is optically translucent to facilitate cleaning.

These and other objects of the present invention, which will become more apparent hereinafter, are basically achieved by forming tubing, for example by extrusion techniques, having a generally homogeneous tubular wall section composed of a relatively flexible material, in which there is embedded a helical strand of relatively stiff, resilient material, extending lengthwise of the wall portion along a helical path about the wall portion. Radiopaque materials are incorporated either in the wall portion or in the strand portion, and the other portion is formed of optically translucent material. Preferably the radiopaque materials are incorporated in the strand portion.

Generally the combination of a relatively flexible wall portion reinforced with a resilient, stiff helical strand is substantially unkinkable, maintains its lumen even on acute flexion and yet is sufficiently flexible for most medical uses, enabling relatively thin wall constructions to maximize flow through the tubing. Such a construction is readily manufactured by co-extrusion, preferably of two melt-extrudable, compatible thermoplastic materials, one, when set, being relatively flexible, and the other, the helical portion, when set, being stiff and resilient. Such coextrusion is readily achieved utilizing apparatus, for example, as described in Meneidis, U.S. Patent 3,642,396. As noted above, either the wall portion or the strand portion should be of radiopaque material to permit visual location of the outside dimensions of the tubing by radiography. Since those materials which impart radiopaque character to plastic materials are, for the most part, pigments which also cause the material to become optically opaque, the other of the wall portion or strand portion should be optically translucent to permit visual inspection of the tubing for cleaning purposes: preferably the radiopaque material is utilized in the helical strand portion of the construction to obtain the most efficient inspection of the tubing for cleaning purposes.

For a more complete understanding of the practical application of this invention, reference is made to the appended drawings, in which:

Figure 1 is a partially sectioned plan view of a length of flexible tubing constructed with accordance of the present invention, and

Figure 2 is a view similar to Figure 1 illustrating flexing of the tubing.

In the drawings the reference numeral 10 generally designates a section of flexible tubing in accordance with the present invention. Tubing 10 basically includes a tubular wall portion 11 formed by extrusion, preferably of a melt-extrudable material, such as a silicone rubber, which after cooling, sets to a relatively flexible homogeneous structure. Embedded in wall portion 11 is a helical strand 12 which is formed by coextrusion with wall portion 11 utilizing a rotating injection port, such that, while the wall portion 11 is extruded as a cylinder, the rotating injection port introduces the material from which strand 12 is formed describing a helical path in the cylindrical portion 11. Strand portion 12 is formed, for example, of a different silicone rubber, which when set is highly stiff and resilient and in which is incorporated a radiopaque pigment, such as calcium carbonate, barium sulfate, bismuth oxychloride or the like.

While combinations of melt-extrudable, compatible materials such as flexible and stiff, resilient silicone rubbers can be utilized to form wall portion 11 and strand portion 12, respectively, other materials and combinations can be employed; for example in place of the stiff resilient silicone rubber, strand 12 can be formed by a coextruded thinner helical band of polysulfone. Polysulfone is particularly useful in combination with the flexible silicone rubber wall portion 11 since the polysulfone is exceedingly stiff and has an extremely high heat deflection temperature which is important in permitting heat sterilization. Other "engineering-type" plastics can be substituted for helical strand 12, by coextrusion with ethylene vinyl acetate copolymer, forming wall portion 11. Polybutylene, polypropylene and ultra high molecular weight polyethylene have sufficient rigidity to prevent kinking of the soft, more flexible ethylene vinyl acetate copolymer. In addition, many different grades of ethylene vinyl acetate copolymer are available some of which are extremely soft and flexible and can be combined with grades that are quite stiff and hard. Still other examples of combinations of melt-extrudable compatible materials include a rigid vinyl strand 12 with a highly plasticized flexible vinyl thermoplastic wall portion 11. Thermoplastic urethane plastics are specially suitable for this application because urethanes adhere well to other plastics and have a wide range of flectural modulus. In addition, glass fibres and other materials can be incorporated into plastics to stiffen them for the purpose of forming strand portion 12. This technique is especially useful with flexible urethane plastic.

Generally, in accordance with this invention, the stiff and less resilient, i.e. rigid, engineering plastic-type material is utilized to form the helical strand which acts as the backbone of the structure and maintains the ... of the

relatively flexible plastic of wall portion 11 during flexion of the tube, as illustrated with reference to Figure 2. At the same time the flexible plastic wall portion 11 can be kept clear, or at least optically translucent, to permit inspection to insure against the accidental inclusion of foreign material and to permit the observation of liquid flow. The radiopaque materials are added to the backbone, that is strand 12. In some circumstances, it may be more desirable to make tubing of wall portion 11 radiopaque and retain the spiral rigid material 12 as an optically translucent strip, as for example to increase the radiopacity of the tubing for some applications.

WHAT I CLAIM IS:

1. Flexible tubing which comprises an extruded, tubular generally homogeneous elongated wall portion and an extruded strand portion embedded in said wall portion by coextrusion therewith extending lengthwise thereof and helically thereabout, one of said wall portion and said strand portion being radiopaque, and the other being optically translucent.

2. Flexible tubing according to claim 1 in which said wall portion is constructed of relatively flexible material, and said strand portion is constructed of stiff, resilient material.

3. Flexible tubing according to claim 1 in which said radiopaque material is said helical strand portion and said optically translucent material is said wall portion.

4. Flexible tubing according to claim 2 in which said radiopaque material is said helical strand portion and said optically translucent material is said wall portion.

5. Flexible tubing substantially as hereinbefore described with particular reference to the accompanying drawings.

For the Applicant,
CARPMAELS & RANSFORD,
Chartered Patent Agents,
43 Bloomsbury Square,
London WC1A 2RA

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1533204 COMPLETE SPECIFICATION

1 SHEET *This drawing is a reproduction of the Original on a reduced scale*

FIG. 1

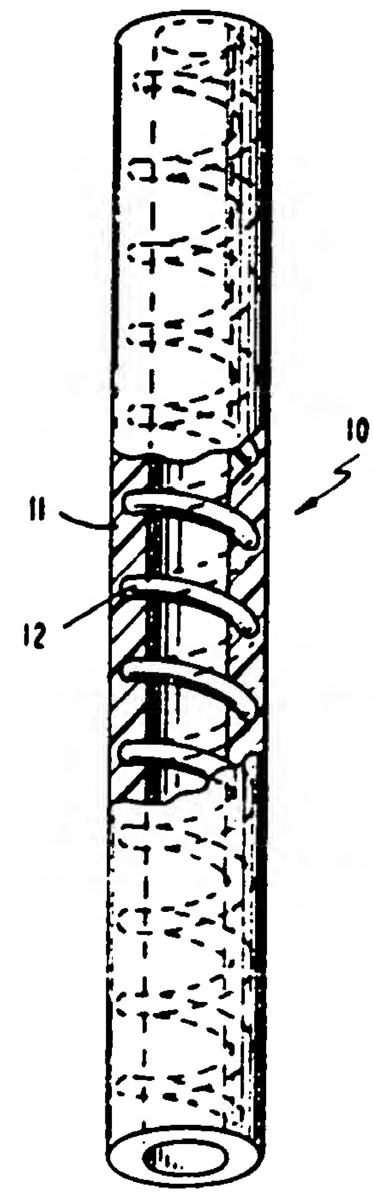

FIG. 2